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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,253	10/12/2001	Paul A. Moore	PF196P1	8837

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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,253	MOORE ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, and/or ClaimsThe amendment submitted 26 July 2004 has been entered. Claims 27 and 29-36 are cancelled. Applicant's election of Invention I (Claims 1-26), in Paper No. 13, is acknowledged. Applicants traversed the Restriction, arguing that claims directed to the nucleotides, antibodies and methods of using the products should be examined together because a search of one invention will reveal art on the related inventions (page 6, 26 July 2004), and that it would not constitute an undue burden to search all claims. However, the claims were properly restricted because searching one product sometimes, but not always, reveals the references pertaining to related products. It is therefore burdensome to perform a complete search on every product. In addition, each product must be searched along with the processes of using the product, resulting in an additional search burden. In addition, as pointed out in the Restriction requirement, distinct products each have independent utilities which cannot be exchanged, thus expanding the terms of a search even further, resulting in further burden.

Claims 10-15 and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions, there being no allowable generic or linking claim.

Claims 1-9 and 16-26 are under examination in the Instant Application.

Claim Rejections/Objections

Claim Rejections - 35 USC § 112, first paragraph -scope of enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-9 and 16-26 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for the nucleic acids of SEQ ID NO: 1, degenerate variants encoding the polypeptide of SEQ ID NO: 2, vectors and isolated host cells comprising same, does not enable polynucleotides encoding variants or fragments of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with the claims.

The claims are directed to the polynucleotides encoding SEQ ID NO: 2, polynucleotides encoding contiguous fragments of SEQ ID NO: 2, vectors and cells comprising the polynucleotides, and methods of recombinantly producing SEQ ID NO: 2. Claims 1-26 encompass polynucleotides encoding polypeptides that are 20-50 contiguous residues and composition. The claims do not require that the short polynucleotides or polypeptide fragments have activity. The scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

The Specification discloses that cells transfected with a polynucleotide encoding SEQ ID NO: 2 resist infection with HIV. Applicants propose that the result is due to the presence of fewer viral receptors on transfected cells and test this hypothesis by staining the cells for CD4 and CxCR receptors; viral receptor levels were lower in transfected cells.

However, the instant Application does not reasonably provide enablement for various fragments of the encoding polynucleotide, since the Specification discloses only use of SEQ ID NO: 1 (i.e., ATCC Deposit No. 97242). The specification is not enabled for the full scope of the polynucleotides, wherein the encoded amino acid sequence is 20-50 contiguous amino acids of SEQ ID NO: 2, with the assurance that enabled proteins that are functionally equivalent to SEQ ID NO: 2 can be made without undue experimentation and with the assurance that they would have the desired properties of SEQ ID NO: 2. There are no examples of what specific polypeptides fall within the range of those fragments that would function identically to SEQ ID NO: 2. Since the claims do not require the variants to have activity, the claims embrace inactive variants. The specification does not disclose how to use such inactive variants. The specific activities of the contiguous fragments are not disclosed. Nor is there disclosed assays to test for these activities. There is no discussion or working examples, disclosed in the instant case, as to what amino acids are necessary to maintain the functional characteristics of the short polypeptide fragments.

Due to the large quantity of experimentation required to determine how to use all active or inactive variants of SEQ ID NO:1 or 2, the lack of direction or guidance in the specification regarding specific activity of fragments of SEQ ID NO: 1 or 2, and the breadth of the claims which embrace innumerable fragments of the polynucleotides of SEQ ID NO: 1 - undue

experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Furthermore, Claims 1 and 16-26 recite polynucleotides deposited as ATCC deposit No. 97272. The portions of these claims reciting the deposited nucleic acids are not enabled for the reasons set forth in the rejection of claims 10-15 for lack of enablement (see below, under Deposit Rules).

35 USC § 112, first paragraph – Written Description.

Claims 1-26 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims are directed to the polynucleotides encoding SEQ ID NO: 2, polynucleotides encoding contiguous fragments of SEQ ID NO: 2, vectors and cells comprising the polynucleotides, and methods of recombinantly producing SEQ ID NO: 2. Claims 1-26 encompass polynucleotides encoding polypeptides that are comprised of 20-50 contiguous residues and compositions comprising.

The specification teaches a polynucleotide (SEQ ID NO: 1) and a polypeptide (SEQ ID NO: 2). However, the specification does not teach functional or structural characteristics of all claimed polynucleotides. The description of one polynucleotide encoding an IRF3 polypeptide is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of protein fragments that have not been produced or adequately identified. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of all claimed polynucleotides and all encompassed polypeptides, and therefore, would not know how to make them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The nucleotide itself is required. See *Fiers v. Revel*, 25

USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1 and a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, first paragraph – Deposit Rules

Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel nucleic acid molecules (i.e., ATCC Deposit No. 97242). Since the nucleic acid molecules are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the nucleic acid molecules are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be

satisfied by a deposit of the nucleic acid molecules. The Specification does not indicate that the deposit was made under the Budapest treaty. If a deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the nucleic acid molecules will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit is not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable. Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the

deposited material sufficient to specifically identify it and to permit examination." At p. 13, the date of the deposit and the address of the depository are missing. The specification should be amended to include such, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification.

The new address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Hall, L.(1993, Accession. No. SSIL2R). Claim 25 recites a polynucleotide that hybridizes to the polynucleotide of Claim 1, under "stringent" hybridization conditions. Hall, L. teaches a DNA that is more than 30% homologous to a polynucleotide which hybridizes to the polynucleotide of SEQ ID NO: 1. Since Claim 25 claims sequences that hybridize to the polynucleotide of Claim 1, under poorly-

defined hybridization conditions, the polynucleotide cited by Hall, L falls within the limits of the claim.

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is rendered indefinite because of the phrase "stringent conditions," which is a conditional term. In other words, for example, some nucleic acids which are able to hybridize under stringent conditions would be unable to hybridize under non-stringent conditions. The metes and bounds of the claim, therefore, cannot be ascertained. This rejection can be overcome by supplying specific conditions, supported by the specification, which the Applicants consider "stringent," or by removing the indefinite phrase.

Claim 26 is rendered indefinite because the specification does not teach how to recombinantly produce a polypeptide from the complementary nucleic acid (refer to claim 1(o)).

Conclusion: Claims 1-26 are rejected for the reasons recited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

24 October 2004

JANET ANDRES
PRIMARY EXAMINER